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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/828,451	04/06/2001	James G. Skakoon	723.031US1	6905

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EXAMINER

ODLAND, KATHRYN P

ART UNIT PAPER NUMBER

3743

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17

Please find below and/or attached an Office communication concerning this application or proceeding.

CD 17

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	09/828,451	SKAKOON ET AL.	
	Examiner	Art Unit	
	Kathryn Odland	3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 15 August 2003.
- 2a) ☐ This action is FINAL.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 90 and 93-114 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 90 and 93-114 is/are rejected.
- 7) ☒ Claim(s) 111 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)                      4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)                      5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 16 .                      6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Response to RCE***

This is a response to the RCE dated August 15, 2003. Claims 90 and 93-114 are pending.

### ***Claim Objections***

1. Claim 111 objected to because of the following informalities: line 4 recites, "an stabilizer." This appears to be a typographical error. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

3. Claim 107 recites the limitation "the electrode" in line 6. There is insufficient antecedent basis for this limitation in the claim. An electrode is not recited until line 7 in the claim.

### ***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 90, 93-109, and 111-114 are rejected under 35 U.S.C. 102(b) as being anticipated by Baudino et al. in US Patent No. 5,927,277.

Regarding claim 90, Baudino et al. disclose a device for immobilizing a primary instrument having a base (such as 10) sized and shaped to be secured about a burr

hole in a skull, as recited in column 1, lines 5-10, and column 2; and coupled to the base, a stabilizer (such as 40) to engage the instrument inserted through the burr hole, the stabilizer including a movable member (such as 52) to define an opening sized and shaped to immobilize the instrument with respect to the burr hole, as recited in columns 5-6 and seen in figures 9-11, for example.

Regarding claim 93, Baudino et al. disclose that as applied to claim 90, as well as, a base (such as 10) having a ring defining an access lumen concentric to the burr hole, as seen in figures 9-11, for example.

Regarding claim 94, Baudino et al. disclose that as applied to claim 99, as well as, a base (such as 10) further having a lip (such as 16) extending circumferentially about the access lumen, the lip sized and shaped to receive and support at least a portion of the stabilizer (such as 52), as recited in column 4, lines 25-65, columns 5-6, and seen in figures 9-11, for example.

Regarding claim 95, Baudino et al. disclose that as applied to claim 94, as well as, a stabilizer (such as 52) that includes a disk, sized and shaped to fit within the base and to be received and supported by the lip, the disk covering at least a portion of the access lumen, as seen in figures 9-11, for example.

Regarding claim 96, Baudino et al. disclose that as applied to claim 95, as well as, a movable member (such as 52) that includes a hinged member (via 50), as recited in columns 5-6 and seen in figures 9-11, for example.

Regarding claim 97, Baudino et al. disclose that as applied to claim 96, as well as, a hinged member (via 50) that includes a cam (via engagement of 46 and 52) that is hingedly coupled to the disk, as recited in columns 5-6 and seen in figures 9-11, for example.

Regarding claim 98, Baudino et al. disclose that as applied to claim 93, as well as, a base (such as 10) that has an exit groove (such as 92) extending outward from the access lumen, the exit groove is sized and shaped to receive at least a portion of the instrument therein to permit the instrument to exit the base, as seen in figure 15B, for example.

Regarding claim 99, Baudino et al. disclose that as applied to claim 90, as well as, a base (10) that has at least one receptacle sized and shaped to receive a mating portion of a cap (such as 90) sized and shaped to substantially cover the access lumen, as seen in figure 15B, for example.

Regarding claim 100, Baudino et al. disclose that as applied to claim 90, as well as, a stabilizer (40) that includes a disk sized and shaped to cover at least a portion of the

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burr hole, and wherein the movable member (such as 52) includes a hinge (via 50), coupling the movable member to the disk; and a catch (via 58), engaging the disk to secure the movable member in a closed position to substantially immobilize the instrument, as recited in columns 5-6 and seen in figures 9-11, for example.

Regarding claim 101, Baudino et al. disclose that as applied to claim 100, as well as, a movable member that includes an engagement (via 42, 44) sized and shaped to receive a tool for moving the movable member to the closed position, as recited in column 5.

Regarding claim 102, Baudino et al. disclose that as applied to claim 90, as well as, a cap (90) sized and shaped to engage the base and substantially cover the burr hole, as seen in figure 15B, for example.

Regarding claim 103, Baudino et al. disclose a device for immobilizing a primary instrument having a ring-shaped base (such as 10), defining an access lumen therethrough; and a stabilizer (such as 40), sized and shaped to be supported within the access lumen, the stabilizer including a disk, including a radial slot; and a movable member (such as 52), hingedly (via 50) coupled to the disk to adjustably overlay a portion of the radial slot to clamp the instrument within the radial slot, as recited in columns 5-6, and seen in figures 9-11, for example.

Regarding claim 104, Baudino et al. disclose that as applied to claim 103, as well as, a movable member (via 52) that includes a catch (such as 58) that engages the disk to restrict movement between the movable member and the disk to clamp the instrument, as recited in columns 5-6, and seen in figures 9-11, for example.

Regarding claim 105, Baudino et al. disclose that as applied to claim 103, as well as, a disk that is 360-degree rotatable within the access lumen to orient the radial slot such that the instrument is capable of being clamped within the radial slot at any desired location within the access lumen, as seen in figures 9-11, where the element 40 can be rotated in any direction within 16.

Regarding claim 106, Baudino et al. disclose that as applied to claim 103, as well as, a base (such as 10) that includes an exit groove (such as 92) extending radially outward from the access lumen, the exit groove is sized and shaped to receive a portion of the instrument, as seen in figure 15B, for example.

Regarding claim 107, Baudino et al. disclose a device having a ring-shaped base (such as 10), sized and shaped to be secured about a burr hole in a skull, the base defining an access lumen therethrough that is concentric to the burr hole, the base including a lip (16) circumferentially surrounding the access lumen, the base further having an exit groove (such as 92) extending outward from the access lumen, the exit groove sized and shaped to receive an electrode therethrough, as recited in column 1, lines 5-10,

column 4, lines 25-65 and columns 5-6; and an electrode stabilizer (such as 40), sized and shaped to be supported on the lip (16) and carried within the access lumen, the stabilizer including a rotatable disk including a radial slot; and a movable member (via 52), hingedly (via 50) coupled to the disk to adjustably overlay a portion of the radial slot, the movable member including a catch (such as 58) fixing a portion of the movable member with respect to the disk to clamp the electrode within the radial slot, as recited in columns 5-6 and seen in figures 9-11, for example.

Regarding claim 108, Baudino et al. disclose a device having a ring-shaped base (such as 10), sized and shaped to be secured about a burr hole in a skull, the base defining a lumen therethrough the is concentric to the burr hole; means (via 40 and associated components), supported by the base and carried within the access lumen, for securing an instrument extending through the access lumen and the burr hole; and a cap (90) couplable to the base sized and shaped to cover the access lumen, as recited in column 1, lines 5-10, column 4, lines 25-65, columns 5-6, and seen in figures 9-11, for example.

Regarding claim 109, Baudino et al. disclose that as applied to claim 108, as well as, one of the base and cap that includes at least one receptacle (the base has the receptacle) and the other of the base and the cap including at least one snap-fit leg (the cap has the snap fit leg, as seen in figure 15A) mating to the at least one receptacle.



Regarding claim 111, Baudino et al. disclose a device having a ring-shaped base (such as 10) defining an access lumen therethrough including a lip (such as 16) circumferentially surrounding the access lumen; a stabilizer (such as 40), sized and shaped to be supported on the lip and carried within the access lumen, the stabilizer including a disk having a radial slot; and a movable member (via 52), hingedly (via 50) coupled to the disk to adjustably overlay a portion of the radial slot, the movable member including a catch (via 58) fixing a position of the movable member with respect to the disk, as recited in column 1, lines 5-10, column 4, lines 25-65, columns 5-6, and seen in figures 9-11, for example.

Regarding claim 112, Baudino et al. disclose a device for immobilizing a primary instrument having a base (such as 10), sized and shaped to be secured about a burr hole opening in a skull, the burr hole opening in the skull defining an external surface of the skull burr hole plane, the base including a lateral stabilizer (via 92) oriented to grasp and immobilize a portion of the instrument passing substantially parallel to the burr hole plane; and coupled to the base a vertical stabilizer (via 40 and associated components) to engage the instrument inserted through the burr hole oriented to grasp and immobilize a portion of the instrument passing substantially perpendicularly to the burr hole plane, as recited in column 1, lines 5-10, column 4, lines 25-65, columns 5-6, and seen in figures 9-11, for example.

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Regarding claim 113, Baudino et al. disclose that as applied to claim 112, as well as, a lateral stabilizer that has a groove (via 92) formed in the base, as seen in figure 15B, for example.

Regarding claim 114, Baudino et al. disclose that as applied to claim 113, as well as, a vertical stabilizer that includes a movable clamp (via 52), the movable clamp capable of motion, in a plane that is substantially parallel to the burr hole plane, providing an adjustably-sized opening, that in an open condition, permits the portion of the instrument passing substantially perpendicularly to the burr hole plane to pass freely through the adjustably sized opening, and in a closed position, grasps and immobilizes the portion of the instrument passing substantially perpendicularly to the burr hole plane, as recited in column 1, lines 5-10, column 4, lines 25-65, columns 5-6, and seen in figures 9-11, for example.

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claim 110 is rejected under 35 U.S.C. 103(a) as being unpatentable over Baudino et al. in US Patent No. 5,927,277.

Regarding claim 110, Baudino et al. disclose that as applied to claim 109. However, Baudino et al. do not explicitly recite, a cap that includes at least one exit groove that is configured to align with at least one other exit groove in the base. On the other hand, it would be obvious to one with ordinary skill in the art to assure the cap of Baudino et al. have at least one exit groove that is configured to align with at least one other exit groove in the base, for the purpose of properly securing the instrument.

### ***Conclusion***

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure are as follows: US Patent No. 6,662,035; US Patent No. 6,609,020; US Patent No. 6,482,182; US Patent No. 6,356,792; US Patent No. 6,321,104; US Patent No. 6,210,417; US Patent No. 6,179,826.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathryn Odland whose telephone number is (703) 306-3454. The examiner can normally be reached on M-F (7:30-5:00) First Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A Bennett can be reached on (703) 308-0101. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9302.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1113.

KO

Henry Bennett  
Supervisory Patent Examiner  
Group 3700

